DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Zee Medical, Inc.
Attn: Kevin Lloyd
Manager, Quality and Regulatory Affairs
22 Corporate Park
Irvine, California 92606

NOV 2 3 1999

Re: Docket No. 98N-0337
Comment No. APP6

Dear Mr. Lloyd:

Please refer to your Application for Exemption dated September 15, 1999, and the facsimile dated October 22, 1999, submitted under 2 1 CFR 20 1.66(e) for Zee Medical, Inc. PainAid ® Pain Relief tablets.

Your application requested an exemption from the labeling requirements for OTC drugs set forth in $201.66 (c)(8) regarding the listing of inactive ingredients on the 0TC drug label; You stated that, because your company obtained bulk tablets from three different suppliers whose formulations contain different inactive ingredients, this requirement is impracticable for your method of manufacturing and distribution. Therefore, you requested to be allowed to use the phrase "may contain" to list inactive ingredients that may or may not be present in the product.

We have completed our review of your request and it is granted for this specific product. Accordingly, you are authorized to present the required information set forth in 21 CFR 20 1.66 (c)(8) for labeling of Zee Medical, Inc. PainAid ® Pain Relief tablets in the following manner:

- The inactive ingredients common to all three formulas (cellulose, FD&C Yellow #6, and starch) should follow the words "Inactive ingredients" as provided for in § 201.66 (c)(8).

- The list of inactive ingredients should then state "may contain" and should only list the following ingredients:
  croscarmelose sodium, D&C yellow #10, magnesium stearate, polyvinylpyrrolidone, silicon dioxide, sodium meta bisulfate, sodium starch glycolate, stearic acid.

This granting of your exemption request does not constitute a full labeling review of this product. The labeling for this product continues to be subject to all other applicable labeling requirements in 21 CFR 201.66, and to any future applicable regulations.

98N-0337

ANS6

The labeling for this product should contain the information listed in § 201.66(c)(9) so that any consumer who has questions about the inactive ingredient information has a telephone number to call for information. You also need to follow all applicable current good manufacturing practice for finished pharmaceuticals regulations in 21 CFR Part 211 so that you have appropriate records of which lot numbers of the product contain which inactive ingredients. You should be able to provide this information readily in response to telephone inquiries.

Please be advised that this approved modification could be suspended if the agency issues specific regulations for the listing of inactive ingredients in OTC drug product labeling. You should also notify the agency if your suppliers' formulations change and, thus, you may need to modify this exemption accordingly.

For a copy of 21 CFR 201.66, please refer to the Dockets Management Branch website located at http://fda.gov/cder/otc/label/label-fr-reg.htm

If you have any questions, please contact Elizabeth F. Yuan, R.Ph., Regulatory Health. Project Manager, at 301-827-2222.

Sincerely yours,

Charles J. Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

copy - 10/22/99

ZEE AMERICA'S WORKPLACE SAFETY EXPERT™

Zee Medical, inc.

FAX TRANSMISSION

To:	Ms, Babette Merritt	From:	Kevin Lloyd
Of:	FDA, Center for Drugs	Company:	Zee Medical, Inc.
Fax No:	301-827-2315	Address:	22 Corporate Park Irvine, CA 92606
Date:	October 22, 1399	Fax No:	949-252-9527
Pages:	1	Phone No:	949-252-9530

This is in response to our phone conversation earlier today concerning our application for exemption from the requirements for listing of inactive ingredients. Shown below are the inactive ingredients for three different formulas for Zee PainAid tablets, which we procure from three different suppliers.

The inactive ingredients common to all three formulas are: cellulose, starch and FD&C Yellow #6.

Supplier 1 Formula (inactives only)

cellulose, croscarmelose sodium, D&C yellow #10, FD&C yellow #6, starch

Supplier 2 Formula (inactives only)

cellulose, croscarmellose sodium, FD&C yellow #6, magnesium stearate, polyvinylpyrrolidone, silicon dioxide, sodium meta bisulfate, sodium starch glycolate, starch, stearic acid

Supplier 3 Formula (inactives only)

cellulose, D&C Yellow #10, FD&C Yellow #6, silicon dioxide, starch, stearic acid

Please call me at 949-252-9530 if you need additional information.